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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,099	11/29/2001	Mary Mowrey-McKee	LP/V-31594/A	3645

1095            7590            03/27/2003

THOMAS HOXIE  
NOVARTIS, PATENT AND TRADEMARK DEPARTMENT  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
1617	A

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/997,099	MOWREY-MCKEE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gina C. Yu	1617	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "quantity insufficient to disinfect a contact lens, but in quantity sufficient to provide preservative efficacy" renders the claim vague and indefinite. Specification does not provide definition of such quantity, rendering the metes and bounds of the scope of the claims unclear.

The term "pharmaceutically active compound" renders claim 20 vague and indefinite. While the term is generally understood to mean drugs or bio-affecting compound, the scope of the term as applied to instant claims are unclear, since applicants' invention as disclosed include an microbicide agent in a buffer solution and ophthalmologically acceptable additives disclosed in specification p. 8 and 9. It is not clear whether the limitation of claim 20 requires a drug or bio-affecting agent, or an ophthalmologically acceptable compound. The metes and bounds of the scope of the instant claim are unclear.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8, 10-15, 18, and 19 are rejected under 35 U.S.C. 102 (a) and (e) as

being anticipated by Tsuzuki et al. (US 6121327) ("Tsuzuki").

Tsuzuki discloses a contact lens disinfecting solution comprising 1 ppm of PHMB (polyhexamethylene biguinide, an disinfecting agent); 1.5 % by weight of propylene glycol; 0.5 % by weight of Bis-Tris buffer, which is 1,3-bis(tris[hydroxymethyl]methylamino)propane meeting the formula and constituents of instant claims 1 and 19; 0.5 % by weight of EDTA salt, a chelating agent in instant claim 11. See Table 4 and 5, specimen no. 7 and 13. The pH of the solutions is said to be 7.2. See col. 1, lines 51 – 67; See instant claim 3. The specimen 13 also contains poloxamers, a surfactant. See instant claims 12 and 13. The solutions are said to contain NaCl, a tonicity agent, meeting instant claims 14 and 15. See col. 11, lines 66-67.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 9, 16, 17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tzusuki as applied to claims 1-8, 10-15, 18, and 19 as above.

The quantity of PHMB in the examples does not appear to meet the limitation of the instant claim 9, "quantity insufficient to disinfect a contact lens, but in quantity sufficient to provide preservative efficacy". The specimens 7 and 13 in Example 2 do not employ viscosity modifiers. As discussed above, the term "pharmaceutically active compound" renders the scope of the claim vague. Examiner assumes, for the purpose of the examination, that the term refers to an ophthalmologically acceptable compound.

Tzusuki teaches that disinfectant is generally used in a concentration of 0.00001-0.1 w/v %, and preferably 0.00005-0.05 w/v % for exhibiting an effective disinfecting or preservative activity. See col. 4, line 60 – col. 5, line 6. The reference further teaches that at a concentration of the disinfectant below 0.00001 w/v %, no effective disinfecting or preservative activity will be obtained. See also col. 6, lines 3 – 9, teaching that 0.1-10 ppm of PHMB is preferably used.

Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Based on the teaching of the general condition in the Tzusuki reference, examiner views that a routineer would have discovered the optimum or workable ranges by routine experimentation to formulate a preservative solution for contact lens.

Tzusuki also teaches that thickeners such as cellulose derivatives are used, since the contact lenses treated with the solutions containing the thickeners smoothly slide on palms and fingers when cleaning the lenses. See col. 4, lines 38 – 44. The reference further teaches that these cellulose derivatives do not adversely affect the properties of the contact lenses during long storage period. See col. 9, lines 1 – 20; See instant claims 16 and 17. Examiner further views that the thickener or surfactant meets the limitation of “pharmaceutically active compound”, See instant claim 20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the disclosed contact lens disinfectant solution formulations in Tzusuki by adding the cellulose thickeners as taught by the reference because of the expectation of successfully producing a solution which provide smoothness to the lenses during cleaning while not adversely affecting the properties of the lenses during long storage period.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner  
March 21, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER  
3/23/03